Validity and reliability of the Body Image Quality of Life Inventory in patients treated for Infective Endocarditis

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ABSTRACT

Rationale and objectives: Suffering through infective endocarditis can drastically alter a person's physical appearance, and body image related concerns have been reported by patients. The extent and severity of the phenomenon has not previously been explored, as no quantitative measure has been validated in this patient population. The purpose of this study was thus to assess the validity, reliability and responsiveness of the Danish Body Image Quality of Life Inventory (BIQLI-DA) on patients treated for infective endocarditis.

Methods: We evaluated the psychometric properties of the BIQLI-DA on data obtained in the CopenHeart IE trial, which is a randomized clinical trial evaluating the effects of comprehensive cardiac rehabilitation for patients treated for infective endocarditis. We administered the BIQLI-DA as part of data collection at baseline and six months. We examined the psychometric properties through correlations to other measures, including Body Mass Index (BMI), Medical Outcome Short Form 36 (SF-36) and Hospital Anxiety and Depression Scale (HADS). In addition we examined internal consistency on item and scale level and performed ANOVA group by time interaction to test for responsiveness.

Results and study limitation: Participants were seventy patients with a mean age of 58 years and of which 83% were men. Results indicated convergent construct validity by confirming hypothesized associations to potentially related constructs. The BIQLI-DA was found to be highly internally consistent with a Cronbach's alpha of 0.96. Instrument responsiveness was indicated by a significant group-by-time interaction. Support for the validity of the BIQLI-DA might have been strengthened by a larger sample with more women. A more optimal design for testing responsiveness would possibly have allowed for clearer conclusions.

Conclusions: The BIQLI-DA may be applicable in health care research as it seems to be valid, reliable and responsive, however evidence should be strengthened through further exploration of instrument performance, particularly regarding responsiveness.

INTRODUCTION

Infective Endocarditis (IE) is an infection of the heart valves and it is among the most serious infectious diseases in the western world (1). Bacteria may invade and destroy the tissue, and vegetations can dislodge into circulation, causing harmful and potentially deadly complications. Treatment requires lengthy hospitalization, high dosage antibiotics and possible valve replacement surgery (1,2).

The pathophysiology and treatment of the disease can drastically alter a person's physical appearance during the course of the illness (3). The infection itself and the antibiotic treatment will often affect the patient's appetite and gastrointestinal function and, as a result, considerable weight loss is common (4). Long term hospitalization, entailing general inactivity and bed rest may also cause loss of muscle mass (5) and surgical interventions related to either cardiac device or heart valve surgery will leave permanent scars on more than 50% of patients (6).

Negative body image has been reported in a number of cardiac populations such as patients with congenital heart disease (7,8), patients with implanted cardiac devices (9,10) and heart transplant candidates (11). Qualitative studies have identified concerns about bodily appearance and sensations in patients with IE (3,12). Patients reported an increased level of attention to body-signals and concerns about interpretation of symptoms, which made them fearful of recurrence (3,12). Furthermore, some patients described their body as being disfigured and emphasized concerns about visible traces, particularly scars and weight loss which kept reminding them of their illness (3,12). Assessment of body image and its impact on patients' lives is important to appraise the extent and magnitude of these problems and to identify potential targets for intervention. For this a valid and reliable instrument is needed.

The Body Image Quality of Life Inventory (BIQLI) was developed by the American psychologist Thomas F. Cash in 2002. It is a 19 item self-report measure that quantifies the influence of the subjects' body image experiences on various relevant facets of psychosocial functioning and wellbeing in everyday life. It uses a 7 point response format ranging from very negative (-3) to very positive (+3) effects of body image on 19 life domains (13). A composite negative score may thus indicate a negative influence of an individual's body image on their quality of life while a positive score may indicate a positive influence. The inventory seemed a good fit for capturing illness related body image concerns, as the focus is on body image as a situational variable trait and of the influence of one's body image on ones quality of life. This makes the inventory especially relevant for measuring body image in relation to a broad range of health conditions and disciplines and also, possibly, to measure sensitivity to change due to health care interventions

The inventory was initially validated on female college students and high internal consistency (Cronbach's alpha = 0.95), good item-total correlations (0.45-0.86) and stability over a 2-3 week period (test-retest reliability = 0.79) were demonstrated (13). Moreover, convergent construct validity was shown by significant relationships with different standardized measures of body image (13). The instrument has subsequently been validated for utilization with both genders (14) and on a wider range of age groups (15). The instrument has been validated in a Spanish version (16) and a Brazilian Portuguese version (17) and has been used in different patient populations (17-23). However, it is not known whether the instrument is valid and reliable for use in IE patients. Therefore, the aims of this study are to test the Danish version of the Body Image Quality of Life (BIQLI-DA) on a sample of patients treated for IE in order to assess: (i) the reliability and validity of the instrument in measuring body image related concerns and (ii) evaluate the instrument's responsiveness to a healthcare intervention.

METHODS

In order to develop a Danish version of the BIQLI-DA, the authors of this article undertook the rigorous process of systematic translation of the original English version and initial validation of the adapted Danish version (BIQLI-DA) on a sample of college students. Results showed support for the semantic equivalence, internal consistency reliability and convergent construct validity of the measure. Results also revealed some concerns about face validity and this issue is discussed (24).

Design and study population

We evaluated the psychometric properties of the BIQLI-DA on data obtained in the CopenHeart IE trial, which is a randomized clinical trial evaluating the effects of comprehensive cardiac rehabilitation for patients treated for IE (25). Exercise training and interventions to improve body awareness have been suggested as interventions to improve adverse outcomes related to body image (26,27). The trial intervention consists of a 12 week individualized training program and a total of five psycho-educational consultations carried out by experienced cardiac care nurses. Trial inclusion commenced in December 2011 and is still on-going. Data collection for the validation study on a subset of participants was completed in January 2015. Recruitment was restricted by the number of eligible participants available for trial participation. The sample initially consisted of 77 patients treated for IE. Three withdrew before initial data collection and an additional four did not complete baseline questionnaires, leaving a sample of 70 respondents (58 men and 12 women) with a mean age of 58 at baseline (BL). At six months (T6) one additional participant had withdrawn, nine did not complete T6 questionnaire and 12 had not yet reached the six month time point, leaving a sample of 48 respondents (42 men and six women) at six months. Selected demographic and clinical characteristics of baseline participants are presented in Table 1.

Data-collection

The BIQLI-DA was included as part of the internet based questionnaire packages used in the CopenHeart IE trial. Paper and pencil administration was possible on request by participants. The BIQLI-DA was included at baseline and at six months and was completed by participants along with a number of other instruments of which two were used in the present study (see section on measures). Additional questions about demographic characteristics were included at baseline. All participants were informed about study purpose, procedures, voluntary participation and anonymity, verbally and in writing.

Psychometric properties

The quality of an instrument is typically assessed by psychometric testing relating to its validity and the reliability (28-31). Validity refers to the extent to which an instrument and/or its subscales reflect the intended construct or phenomenon (28). We assessed the validity of the BIQLI-DA by examining hypothesized correlations to other measures. Reliability refers to the consistency, stability and dependability with which an instrument measures the construct or phenomenon it aims for (29). We assessed the reliability of the BIQLI-DA on this sample by examining its internal consistency on scale and item level. We also assessed the responsiveness of the BQLI-DA, which refers to the instrument's ability to detect an important change over time in the construct to be measured (32). Assessing the responsiveness of the BIQLI-DA allows us to determine its appropriateness as an outcome parameter in clinical trials.

Hypotheses

Based on prior research findings, the following hypotheses were generated and tested in order to obtain evidence that supports validity in relationship to other variables.

Hypothesis 1: Body image quality of life is negatively associated with BMI in women. This relationship has been shown in other studies in younger women (13,14,16) .

Hypothesis 2: Body image quality of life is positively associated with increasing age. A more positive body image quality of life has been shown to be related to increasing age (15).

Hypothesis 3: Body image quality of life is negatively associated with estimated weight loss. Qualitative studies find that patients have concerns about bodily changes that commonly occur during illness, such as weight loss (3,12).

Hypothesis 4: Body image quality of life is positively associated with self-rated physical health as measured by the Physical Component Score (PCS) of the SF-36, where higher scores indicate better perceived physical health. Qualitative findings reveal that patients have an increased awareness of their bodies and physical symptoms after illness (3,12).

Hypothesis 5: Body image quality of life is positively associated with self-rated mental health as measured by the Mental Component Score (MCS) of the SF-36, where higher scores indicate better perceived mental health. This association was demonstrated in the initial validation study of the Danish version of the BIQLI-DA (24).

Hypothesis 6: Body image quality of life is negatively associated with anxiety as measured by the Hospital Anxiety and Depression scale (HADS), with higher scores indicating higher anxiety levels. This association has been found in the initial validation study of the BIQLI-DA (24).

Hypothesis 7: Body image quality of life is negatively associated with indicators of depression as measured by the HADS, with higher scores indicating signs of depression. This relationship was also shown in the initial BIQLI-DA validation study (24).

Due to the exploratory nature of this study, we chose to examine correlations on men and women separately, as well as in the total sample. We expected weak to moderate correlations as we were measuring potentially related but different concepts. We used Cohen's proposition for cut-offs for correlation coefficients: > 0.1 = small; >0.3 = moderate; > 0.5 = strong (33).

Measures

In order to test the hypotheses, data from other measures were collected. The choice of measures was restricted by their availability in Danish.

Body Mass Index (BMI) (34) is a measure of an individual's weight, divided by the square of their height (kg/m^2). A high body mass can be an indicator of high body fatness. It is commonly used to assess how much an individual's body weight deviate's from what is recommended for his or her height.

The Medical Outcome Scale Short Form 36 (SF-36) is a measure of self-rated health. It uses 36 items to measure eight components: physical functioning (PF), role-physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role-emotional (RE) and mental health (MH). Scores are calculated for each component and aggregated into two summary scores, a mental component score (MCS) and a physical component score (PCS). Factor analysis studies have confirmed physical and mental health factors that account for 80% to 85% of the reliable variance in the eight scales (35). Scores range from 0 to 100 with higher scores indicating better perceived health (36,37). With rare exceptions, published reliability statistics have exceeded the minimum standard of Cronbach's alpha of 0.70 recommended for measures used in group comparisons in more than 25 studies (38) and most have exceeded 0.80 (39-41). Reliability estimates for physical and mental summary scores usually exceed 0.90 (42). The SF-36 health survey has been validated in Danish (43,44).

Hospital Anxiety and Depression Scale (HADS) is a 14-item questionnaire that assesses levels of depression and anxiety in medically ill patients. The scale offers two scores, HADS-A and HADS-D and consists of seven questions to assess anxiety and seven questions to assess depression (45). For each of the questions the respondent chooses from four responses to indicate the frequency/extent to which each applies for the last week. The HADS has been

demonstrated to be valid and internally consistent, with a mean Cronbach's alpha of 0.83 and 0.82 for the HADS-A and HADS-D respectively (46). To our knowledge validation studies on the HADS in Danish have not been published.

Statistical analysis

Statistical analyses were performed using the IBM SPSS® 20.0 software package. Prior to analysis, data were examined for missing data, variables' distribution and relationships in order to choose the appropriate statistical models for analyses. Hypothesized correlations were investigated using Spearmann's rank order correlation coefficient as data were not normally distributed. Descriptive statistics were performed to quantify demographic characteristics. Internal consistency of measures was determined using Cronbach's alpha. In order to test instrument responsiveness, we performed ANOVA group-by-time interaction as a way of comparing change in body image as measured by BIQLI-DA over time between the intervention and the control group of the CopenHeart IE trial. Except for the ANOVA, all analyses were on baseline data. For relevant analyses, significance level was set at 0.05.

RESULTS

Validity

Convergent construct validity was examined through correlations with the previously mentioned variables. Results are shown in Table 2. All of our hypotheses of weak to moderate correlations between the BIQLI-DA and related traits were confirmed. In the gender-specific analyses, some correlations were quite weak or non-existent. This was especially the case in self-rated physical and mental health, where no association is found in women for physical health and none for men in mental health. For the remainder of the variables, the magnitude of the associations in women compared to men was noticeably higher and in several cases associations were strong.

Reliability

Internal consistency reliability determined by Cronbach's alpha of the BIQLI-DA was 0.96 for this sample at baseline, demonstrating excellent internal consistency between items, exceeding the recommended minimum of 0.70 for a respectable alpha (28). Corrected item-total correlations ranged from 0.61 to 0.86 with no items demonstrating poor correlation or an increase in Cronbach's alpha if deleted, as shown in Table 3.

Responsiveness

Figure 1 shows the baseline and T6 BIQLI-DA scores for the intervention and control groups in the CopenHeart IE trial. The analysis was performed on the 48 participants who had completed the BIQLI-DA at both baseline and T6. Means at baseline were 0.7 and 1.5 for the intervention and control group respectively and means at T6 were 0.8 and 1.1 respectively. We found a significant group-by-time interaction between the two groups; those who received the CopenHeart IE intervention and those who did not ($p = 0.03$), indicating a significant difference in body image scores between groups over time and thus suggesting the responsiveness of the BIQLI-DA.

DISCUSSION

This study examined the psychometric properties of the Danish Body Image Quality of Life Inventory (BIQLI-DA) on a sample of patients treated for infective endocarditis in order to evaluate its applicability in health care research.

Validity based on relationships to other variables was demonstrated by confirmation of the seven hypotheses. The correlations were generally weak, especially for men, but this was in line with the expectations. Results demonstrated an association between body image quality of life and BMI, particularly in women, which is consistent with previous findings (14,16,17). Based on patient reports in qualitative studies, we also tested and confirmed a hypothesized

association between body image quality of life and weight loss. This may seem to contradict the BMI association, however, in this population patients report that weight loss is perceived as a negative consequence of long standing disease which has altered their appearance negatively (12). Hence the weight loss related to the deleterious effects of disease and treatment on the body seems to affect a person's body image and this association, as well as the known association with overweight, can both be detected in this sample. The relatively broad age range in our study allowed us to test the correlation between age and body image quality of life. Studies have shown that increasing age is correlated to higher BIQLI scores, particularly in men (15) and this association was confirmed in our study for men, as well as for women. The assumption that body image quality of life is related to self-rated mental health, anxiety and depression was confirmed in this sample mainly in women, but for depression also in men, thus supporting the validity of the BIQLI-DA. In our initial validation study we provided first time evidence of an association between the mentioned indicators of mental health and body image quality of life (24). This study confirms such relationships by demonstrating noticeable correlations, particularly in women, in this sample of patients treated for IE. The association to self-rated physical health, however, is quite weak and non-existent for women. This was slightly surprising to us, as the qualitative findings had indicated that body image concerns in IE patients may be less linked to physical appearance and more to bodily sensations and functioning, which we presumed to be related to physical health. This association was not clear in our sample. The instrument shows excellent internal consistency and high corrected item-total correlations in this sample. These finding are similar to previous reports (13,14,16,17). We found a significant group-by-time interaction indicating differential change over time between groups, thus suggesting the responsiveness of the BIQLI-DA and its applicability in intervention studies. This way of testing responsiveness however is encumbered by possible misinterpretation as we cannot be sure the

change detected is an affirmation of sensitivity of the instrument and there are no prior studies supporting our findings.

METHODOLOGICAL CONSIDERATIONS AND RESEARCH DIRECTIONS

A process of systematic translation and validation preceded this study, ensuring instrument equivalence and initial evidence of instrument validity and reliability. Consistent with previous findings, the psychometric testing on patients treated for IE supports the conclusion that the BIQLI-DA is a valid and reliable measure however conclusions are restricted by sample size and characteristics, particularly the small proportion of women. The scant availability of valid measures in Danish limited our choice of methods. Access to other measures of body image and not merely related constructs, would have been optimal in providing evidence of convergent validity and would have enabled us to examine the magnitude and direction of change over time between measures of the same construct as a way of testing responsiveness. As we detected some issues with the face validity in the initial validation study, it might have been advantageous to do cognitive interviews in the IE sample, in order to assess comprehensibility in this population. The study might also have been strengthened by having been designed and performed independently of the CopenHeart IE clinical trial. Questionnaire administrations at baseline and six months were both quite extensive (215 and 260 items respectively) and the BIQLI-DA was placed last in both. This may have resulted in response fatigue and affected the accuracy of results.

Further studies on larger samples are needed in order to explore the validity of the measure in patient populations and also to explore whether an instrument including bodily sensations and functioning may be more suitable for capturing body image concerns in people who have suffered from IE or other acute or chronic illness. Lastly, additional testing on other patient populations is needed, to establish the applicability and appropriateness of the BIQLI-DA

both as a measure in descriptive studies, and also whether the instrument is sensitive to change due to health care interventions and can be used in randomized clinical trials.

CONCLUSION

Our results show support for the validity, reliability and responsiveness of the BIQLI-DA in patients treated for IE. However, based on the experiences of our initial validation study and methodological limitations of this study, we see that there might be an issue concerning certain aspects of validity. This issue should be explored further before the use of the BIQLI-DA for interventional healthcare research can be fully supported.

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AUTHOR CONTRIBUTIONS

TBR, HK, and SKB designed the study and conducted data collection. TBR and JD conducted the data analysis. TBR in collaboration with JD, HK, PM, ADZ and SKB drafted the manuscript. All authors revised the manuscript critically and have given their final approval of the version to be published.

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ETHICAL APPROVAL

The CopenHeart IE trial has been approved by the Regional Research Ethics Committee (no H-1-2011-129) and the Danish Data Protection Agency (no 2007-58-0015). The study complies with the latest Declaration of Helsinki and is registered at ClinicalTrials.gov (NCT01512615).

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Table 1. Demographic and clinical characteristics of participants

	BL (n = 70)
Male sex, *n* (%)	58 (82.9)
Age in years, mean (±SD)/ range	58.0 (14.2) / 22 - 83
Married/Domestic partner, *n* (%)	49 (70.0)
Type of IE: • Left-sided (Native- or prosthetic heart valve, aortic-, mitral- or both), *n* (%)	57 (81.4)
• Cardiac device (PM[1], ICD[2], CRT-P or -D[3]), *n* (%)	10 (14.3)
• Left-sided heart valve and cardiac device, *n* (%)	3 (4.3)
Type of surgery: • Heart valve surgery, *n* (%)	32 (45.7)
• Device surgery, *n* (%)	9 (12.9)
• Heart valve- and device surgery, *n* (%)	2 (2.9)
• No surgery, *n* (%)	27 (38.6)
Weight-loss in kilograms, mean (±SD)/ range	5.0 (5.0) / 0 - 18
BMI in kg/m2, mean (±SD)/ range	25.9 (4.2) / 17.9 - 42.4
Intervention group, *n* (%)	(36) 51.4%

Weight loss is a self-reported estimate by patients.
PM[1] = Pacemaker, ICD[2] = Implantable Cardio Defibrillator, CRT-P or -D[3] = Cardiac Resynchronization Therapy - Pacemaker or -Defibrillator

Table 2. Correlation the BIQLI-DA and other measures

Measures	**Spearman's Correlation Coefficient [1] (*r*)**		
Name (+ subscales)	**Total sample (*N* = 70)**	**Men (*N* = 58)**	**Women (*N* = 12)**
Body Mass Index (BMI)	- 0.26*	- 0.26*	- 0.40
Estimated weight loss #	- 0.24	- 0.15	- 0.60
Age	0.30*	0.30*	0.38
Medical Outcome Short Form - 36 (SF-36)			
Physical Component Score (PCS)	0.14	0.18	0.06
Mental Component Score (MCS)	0.12	0.04	0.49
Hospital Anxiety and Depression Scale (HADS)			
HADS-A (Anxiety scale)	- 0.20	- 0.15	- 0.56
HADS-D (Depression scale)	- 0.42**	- 0.43**	- 0.50

[1] Bivariate analyzes, # only on the 50 patients who had had weight loss
* $p < 0.05$, ** $p < 0.01$.

Table 3. Reliability Statistics

Item	Corrected item-total Correlation	Cronbach's Alpha if item Deleted
1. My basic feelings about myself – feelings of personal adequacy and self-worth.	0.77	0.959
2. My feelings about my adequacy as a man or woman - feelings of masculinity or femininity.	0.72	0. 959
3. My interactions with people of my own sex.	0.74	0. 959
4. My interactions with people of the other sex.	0.80	0.958
5. My experiences when I meet new people.	0.77	0. 959
6. My experiences at work or at school.	0.70	0.960
7. My relationships with friends.	0.74	0. 959
8. My relationships with family members.	0.77	0. 959
9. My day-to-day emotions.	0.86	0.957
10. My satisfaction with my life in general.	0.81	0.958
11. My feelings of acceptability as a sexual partner.	0.70	0.960
12. My enjoyment of my sex life.	0.71	0. 960
13. My ability to control what and how much I eat.	0.66	0. 960
14. My ability to control my weight.	0.71	0. 960
15. My activities for physical exercise.	0.68	0. 960
16. My willingness to do things that might call attention to my appearance.	0.61	0.961
17. My daily "grooming" activities (i.e., getting dressed and physically ready for the day).	0.67	0. 960
18. How confident I feel in my everyday life.	0.81	0. 958
19. How happy I feel in my everyday life.	0.83	0.958

Figure 1. ANOVA group-by-time interaction